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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,759	06/21/2006	Sobhi Saub	32102	8697
67801 7590 11/24/2008 MARTIN D. MOYNIHAN d/b/a PRTSI, INC. P.O. BOX 16446 ARLINGTON, VA 22215				
EXAMINER				
MI, QIUWEN				
ART UNIT		PAPER NUMBER		
1655				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/583,759

**Applicant(s)**

SAUOB ET AL.

**Examiner**

QIUWEN MI

**Art Unit**

1655

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 103-118, 126-147 and 149-186 is/are pending in the application.
- 4a) Of the above claim(s) 103-114, 126-128, 130-140, 145-147 and 150-183 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 115-118, 129, 141-144, 149 and 184-186 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/21/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's amendment in the reply filed on 10/16/08 is acknowledged, with the cancellation of Claims 1-102, 119-125, and 148; and the additional newly added Claims 184-186. Claims 103-118, 126-147, and 149-186 are pending. Claims 103-114, 126-128, 130-140, 145-147, and 150-183 are withdrawn as they are directed toward a non-elected invention groups or species. **Claims 115-118, 129, 141-144, 149, and 184-186 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

### **Claim Rejections –35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 141-144, and 149 remain rejected under 35 USC § 102 (b) as being anticipated by Bae et al (KR 2001004857 A), as evidenced by Kin et al (JP 63208531 A).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 4/16/2008, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Bae et al teach that *Portulaca oleracea* extract is provided for manufacturing a functional drink. *Portulaca oleracea* is heated with hot water (a pharmaceutical acceptable carrier) (thus a polar fraction extract) or dissolved with ethanol solvent (a pharmaceutical acceptable carrier) (thus a polar fraction extract), then compressed or filtered to make extract. The extract is processed to a liquid or powder phase (see Abstract, full translation has been ordered).

As evidenced by Kin et al, water extract of *Portulaca oleracea* is effective against diabetics, and lowers blood sugar value of the diabetics (see Abstract, full translation has been ordered).

It is noted that Bae et al do not teach hydrocolloids, thus the limitations of claims 120 and 149 are met.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use to lower glucose levels in the blood or increase glucose transport into cells and/or decrease glucose adsorption through the intestines. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims.

Since the prior art teaches the same plant material *Portulaca oleracea* and the same polar fraction extract as claimed, it is deemed that fraction/extract in the prior art contains the same chemical components that has the same Rf values in TLC as claimed.

Therefore, the reference is deemed to anticipate the instant claim above.

Applicant argues that “Applicant wishes to point out to that the pharmaceutical composition of Claim 141 is limited by comprising a therapeutically effective amount for reducing blood glucose levels. Since Bae et al does not teach the use of *Portulaca oleracea* L compositions for lowering blood glucose levels, but rather for use as an antimicrobial or anti cancer agent, Applicant contends that the pharmaceutical compositions of Bae et al do not comprise the same amounts of extract and as such cannot be used to anticipate the presently claimed pharmaceutical composition” (page 6, 3<sup>rd</sup> paragraph).

This is not found persuasive. Since the cited reference teaches the claimed plant material being extracted with the claimed solvent, the extract is deemed to have the claimed activity regardless whether it is being explicitly taught by the reference or not. Therefore, the reference is deemed to anticipate the instant claim above.

Claims 184-186 are newly rejected under 35 USC § 102 (c) as being anticipated by Kang et al (KR 2003047457A).

This is a new rejection necessitated by the Applicant’s amendment filed on 10/16/08.

Kang et al teach a cosmetic composition for preventing and curing the acne is prepared with (wt.%) extract of *Portulaca oleracea* (0.001 - 30), copper gluconate (0.01 -2), zinc gluconate (0.01 - 2), and magnesium gluconate (0.5 - 20), by washing *Portulaca*, pulverizing to form powder, adding water and 1,3-butyleneglycol (or ethanol) (thus a mixture of ethanol and water) in a volume ratio of 2:1, mixing for 1 - 2 weeks, filtering, concentrating, and freeze-drying (see Abstract, the rejection is based on the Abstract).

Therefore, the reference is deemed to anticipate the instant claim above.

#### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 115-118, 129, 141-144, 148, and 149 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bae et al (KR 2001004857 A), as evidenced by Kin et al (JP 63208531 A).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 4/16/2008, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Bae et al teach that *Portulaca oleracea* extract is provided for manufacturing a functional drink. *Portulaca oleracea* is heated with hot water (a pharmaceutical acceptable carrier) (thus a polar fraction extract) or dissolved with ethanol solvent (a pharmaceutical acceptable carrier) (thus a polar fraction extract), then compressed or filtered to make extract. The extract is processed to a liquid or powder phase (see Abstract, full translation has been ordered).

As evidenced by Kin et al, water extract of *Portulaca oleracea* is effective against diabetics, and lowers blood sugar value of the diabetics (see Abstract, full translation has been ordered).

It is noted that Bae et al do not teach hydrocolloids, thus the limitations of claims 120 and 149 are met.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use to lower glucose levels in the blood or increase glucose transport into cells and/or decrease glucose adsorption through the intestines. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims.

Since the prior art teaches the same plant material *Portulaca oleracea* and the same polar fraction extract as claimed, it is deemed that fraction/extract in the prior art contains the same chemical components that has the same Rf values in TLC as claimed.

Bae et al do not teach an ethanol-water extract with the claimed ratio, or a solvent of methanol: ethanol: water in proportions of 1:1:1.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the ethanol-water extract since Bae et al teach extracting *Portulaca oleracea* with water and ethanol, and since ethanol and water are often used in a mixture as a conventional solvent in the art. It would have been *prima facie* obvious for one of ordinary skill in the art to add methanol into the mixture of ethanol and water, as methanol and ethanol are used interchangeably in the art since they have similar polarities, and adding methanol to the mixture reduces the boiling temperature of the mixture solvent so that the heat-labile components would not be altered. Regarding the limitation to the claimed ratio of ethanol-water, or the ratio of methanol: ethanol : water, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on polarity and stability of the active components in the plant.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that "The Examiner's rejection is respectfully traversed. Applicant wishes to point out that extraction using a combination of water and ethanol is superior and



synergetic to the use of water or ethanol alone and thus, the resultant composition cannot be obviated using the art of Bae et al. The superiority of the ethanol-water extract is exemplified in the present specification by its outstanding and surprising results - see for example Page 38, lines 24-28: *"In both groups of Type 2 diabetes patients, a remarkable reduction in the level of blood glucose was observed. Diabetic patients whose blood glucose at the start of trial was less than 300 mg/dl maintained normal blood glucose levels after 2 - 3 weeks. Normal blood glucose levels were attained after 4 - 5 weeks in the group of diabetic patients with initial levels that were greater than 300 mg/dl"* page 7, 2<sup>nd</sup> and 3<sup>rd</sup> paragraph). Applicant further argues that "Applicant further wishes to point out that ethanol has different polarity, miscibility and extraction properties as those of methanol, and therefore use of methanol is not obviated by Bae et al" (page 7, 4<sup>th</sup> paragraph). Further more, as indicated above, it would have been *prima facie* obvious for one of ordinary skill in the art to add methanol into the mixture of ethanol and water, as methanol and ethanol are used interchangeably in the art since they have similar polarities, and adding methanol to the mixture reduces the boiling temperature of the mixture solvent so that the heat-labile components would not be altered.

This is not found persuasive. According to MPEP 716.02 (a), a greater than additive effect is not necessarily sufficient to overcome a *prima facie* case of obviousness because such an effect can either be expected or unexpected. Applicants need further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte* The NutraSweet Co., 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991). In the instant case, Applicant needs to

present a side by side comparison between the claimed invention and the closest art to show the allegedly surprising results, mere argument or allegation is insufficient to overcome the obviousness rejection. For instance, Applicant needs to present a side by side comparison between the water extract and ethanol extract from Bae and the claimed extract methanol:ethanol:water in proportions of 1: 1:1 show the allegedly surprising results.

Applicant argues that “In addition, Applicant contends that the art of Kin cannot be used in combination with Bae et al to obviate the presently claimed invention since Kin specifically states that only compositions that have been prepared by soaking whole portulaca plants in warm water and then subsequently dried for 60 days or longer can be used to treat diabetes - see page 3 of the translation enclosed herein: *The present invention is characterized by soaking whole portulaca plants in warm water and subsequently drying them for 60 days or longer without exposing them to direct sunlight. Only when portulaca is processed in this manner does it become possible to extract from portulaca an essence that dramatically lowers the blood sugar level of diabetic patients*” (page 7, 5<sup>th</sup> and 6<sup>th</sup> paragraph). Applicant further argues that “As such Kin et al teaches away from using an ethanol:water extract or an ethanol:water:methanol extract for lowering blood glucose levels” (page 7, last paragraph).

This is not found persuasive. First of all, Kin et al reference is cited merely to relay an intrinsic property and is not used in the basis for rejection *per se*. Secondly, Kin et al does not does not criticize, discredit, or otherwise discourage the claimed combination of solvent. Bae et al teach not only the hot water extract, but also the ethanol extract, since the claimed plant

material being extracted with the claimed solvent, the extract is deemed to have the claimed activity regardless whether it is being explicitly taught by the reference or not.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

### **Conclusion**

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michael V. Meller/

Primary Examiner, Art Unit 1655